

**REMARKS**

The Office Action dated April 19, 2006, has been received and reviewed. Claims 1 through 10 are currently pending in the application. Claims 1 through 6 stand rejected. Claims 7-10 are added. No new matter has been added. Applicants have amended claims 1 and 6. All amendments are made with prejudice or disclaimer. All claims stand rejected. Applicants respectfully request reconsideration.

In the Specification, paragraph [0013] has been amended to include SEQ ID NO:39 to the amino acid sequence presented. It is respectfully submitted that the specification, as originally filed, supports the substitute SEQUENCE LISTING included herein. Enclosed are the following items in connection with the above-referenced application: Statement under 37 C.F.R. §§ 1.821 through 1.825, paper copy of sequence listing; CRF copy of sequence listing.

Support for new claims 7-10 can be found throughout the specification and more specifically at paragraph [0007]-[0008].

**Claim Objection**

Claim 6 is objected to and the Office suggests to replace “*in vitro*” with “isolated.” *Office Action* dated April 19, 2006, page 3. Applicants have done so, and, accordingly, request the withdrawal of the objection to claim 6.

**35 U.S.C. § 112, second paragraph, Indefiniteness Rejections**

Claims 1-6 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection, as hereinafter set forth.

The Office alleges that claims 1 and 6 are “vague and indefinite because of the claim recitation ‘fibroblast-like or macrophage-like cells.’” *Office Action* dated April 19, 2006, page 3.

The Federal Circuit has held that “[a] patent need not teach, and preferably omits, what is well known in the art.” *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987). Applicants respectfully submit that the terms “fibroblast-like” and “macrophage-like” are well known in the art, and a person of ordinary skill in the art would understand the meaning of “fibroblast-like cells” and “macrophage-like cells.” The terms “fibroblast-like cells” and “macrophage-like cells” do not simply refer to cells of similar composition as macrophage and

fibroblast cells but are the names of distinct sets of cells found in the synovial cavity. The terminology has been in long use. *See, e.g.,* Kitamura et al., “Unique Localization of Protein Gene Product 9.5 in Type B Synoviocytes in the Joints of the Horse”, *The Journal of Histochemistry and Cytochemistry*, 47(3):343-351 (1999) (accepted for publication in October 1998). The terminology has continued in use to this day. *See, e.g.,* G. Firestein, “Immunologic Mechanisms in the Pathogenesis of Rheumatoid Arthritis”, *J. Clin. Rheumatol.*, 2005; 11: S39-S44, page S40, paragraph 4; Fowler et al. “Synovial Metaplasia, A Specialized Form of Repair”, *Arch. Pathol. Lab. Med.* 2002; 126:727-730, pages 728-729; Hanyuda et al. “Activated leucocytes express and secrete macrophage inflammatory protein-1 $\alpha$  upon interaction with synovial fibroblasts of rheumatoid arthritis via a  $\beta_2$ -integrin/ICAM-1 mechanism”, *Rheumatology* 2003; 42:1390-397, page 1391, paragraph 1; and *Interleukin-1 receptor antagonist intervenes in signaling between different types of synoviocytes in rats with adjuvant arthritis*, *Acta Pharmacologica Sinica* 2006 January; 27 (1): 111-118, page 112, paragraph 2. Accordingly, Applicants respectfully request the withdrawal of the 35 U.S.C. § 112, second paragraph, indefiniteness rejections of claims 1 and 6 and reconsideration of same.

As claims 2-5 are dependent from claim 1, which contained the terminology, the rejection should be withdrawn as to these claims too.

The Examiner further thought that claim 6 was “vague and indefinite because of the claim recitation ‘fibroblast-like or macrophage-like cells having been provided with a nucleic acid of interest.’” *Office Action* dated April 19, 2006, page 3. As indicated in the Office Action, it was thought that the term “provided” makes it “unclear whether the claim encompasses untransfected fibroblast-like cells, and the metes and bounds of the claims are uncertain.” *Id.*

Although the Applicants do not agree with the rejection, to expedite prosecution, claim 6 has been amended herein. In particular, claim 6 has been amended to replace the recitation “provided with a nucleic acid of interest” with “infected with a recombinant adenovirus.” Basis for the amendment to claim 6 can be found throughout the specification and more specifically at paragraphs [0013] and [00117]. Accordingly, Applicants respectfully request the withdrawal of the 35 U.S.C. § 112, second paragraph, indefiniteness rejection of claim 6 and reconsideration of same.

**35 U.S.C. § 112, first paragraph, Written Description Rejections**

Claims 1-6 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly lacking a proper written description. Applicants respectfully traverse the rejection.

The Office alleges that claims 1 and 6 lack a written description because “the characteristics of fibroblast-like or macrophage-like cells are not as well-defined [as fibroblasts and macrophages] and the specification does not define the term[s].” *Office Action* dated April 19, 2006, page 5.

As previously noted, the terms “fibroblast-like” and “macrophage-like” are well known in the art and a person of ordinary skill in the art would understand the specific meaning of “fibroblast-like cells” and “macrophage-like cells.” The terms “fibroblast-like cells” and “macrophage-like cells” do not simply refer to cells of similar composition as macrophage and fibroblast cells but are the names of distinct sets of cells found in the synovial cavity. Further, although the Applicants do not agree with the Office’s interpretation of claims 1 and 6, to expedite prosecution, claim 1 is amended herein. In particular, claim 1 is amended to include the recitation “said cell being isolated from a synovial cavity.” The characteristics of fibroblast-like and macrophage-like cells associated with the synovial cavity are well known in the art. *See* references noted *supra*. Accordingly, Applicants respectfully request the withdrawal of the 35 U.S.C. § 112, first paragraph, written description rejections of claims 1 and 6 and reconsideration of same.

As claims 2-5 are dependent from claim 1, which contained the rejected terminology, the rejection should be withdrawn as to these claims too.

**35 U.S.C. § 112, first paragraph, Enablement Rejections**

Claims 1-6 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly not being enabled. Applicants respectfully traverse the rejection.

The Office alleges that claim 1 does not “provide enablement for delivering a nucleic acid of interest specifically or preferably to fibroblast-like or macrophage-like cells other than those associated with the synovial cavity.” *Office Action* dated April 19, 2006, page 7.

Although the applicants do not agree with the rejection, to expedite prosecution, independent claim 1 has been amended herein to recite that “said cell being isolated from a

synovial cavity.” Accordingly, applicants respectfully request the withdrawal of the 35 U.S.C. § 112, first paragraph, enablement rejection of claim 1. As claims 2-5 are dependent from claim 1, which was the basis of the rejection, the rejection should be withdrawn as to these claims too.

### 35 U.S.C. § 102

#### Anticipation Rejection Based on D’andrea et al (Biochem J. 1998; 329:681-7)

Claim 6 stands rejected under 35 U.S.C. § 102(b) as being anticipated by D’andrea *et al.* (Biochem J. 1998; 329:681-7). Applicants respectfully traverse this rejection, as hereinafter set forth.

The Office alleges that claim 6 is anticipated by D’andrea because “as written [the claim] encompasses any unmodified or modified synovial cells.” *Office Action* dated April 19, 2006, page 9.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102.” *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Although the Applicants do not agree with the Office’s interpretation of claim 6, to expedite prosecution, claim 6 has been amended herein. In particular, claim 6 is amended to include the recitation “[a]n isolated fibroblast or a macrophage cell having been infected with a recombinant adenovirus” (emphasis added). Basis for the amendment to claim 6 can be found throughout the specification and more specifically at [0013] and [00117]. Applicants respectfully submit that claim 6, as amended, is not anticipated by D’andrea because D’andrea does not describe each and every element of claim 6 as amended. Specifically, D’andrea does not describe a synovial cell “infected with a recombinant adenovirus.” Accordingly, Applicants respectfully request the withdrawal of the 35 U.S.C. § 102(b), anticipation rejection of claim 6 and reconsideration of same.

#### Provisional Anticipation Rejection Based on co-pending Application No. 10/305,435

Claims 1-6 stand provisionally rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by the co-pending Application No. 10/305,435. Applicants respectfully traverse this rejection, as hereinafter set forth.

The Office alleges that claims 1-6 are provisionally anticipated by co-pending Application No. 10/305,435 “based upon the earlier effective U.S. filing date of the copending application.” Under 35 U.S.C. § 102(e) “[a] person shall be entitled to a patent unless the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent...” (emphasis added). 35 U.S.C. §102(e). Application No. 10/305,435 has a filing date of November 25, 2002 and claims priority to November 29, 2001. However, as stated at paragraph [0001] of the instant Specification, the priority date of this application is March 5, 1999. Therefore, application U.S.S.N. 10/305,435 was not “filed in the United States before the invention by the applicant for patent.” Accordingly, applicants respectfully request the withdrawal of the 35 U.S.C. § 102(e), provisional anticipation rejections of claims 1-6 and reconsideration of same.

Should this provisional rejection remain after consideration of the foregoing, applicants will address the rejections upon allowance of one set of claims or the other.

Inventorship Rejection Based on Co-pending Application No. 10/305,435

Claims 1-6 stand rejected under 35 U.S.C. § 102(f) as allegedly not being invented by applicants in light of co-pending, co-owned Application No. 10/305,435. Applicants respectfully traverse this rejection.

The Office alleges that the applicants did not invent the claimed subject matter because “[t]he copending Application No. 10/305,435 anticipate[s] instant claims but has a different inventive entity. It is unclear who is the real inventor.” *Office Action* dated April 19, 2006, page 10. As previously noted, Application No. 10/305,435 claims priority to November 29, 2001 while claims 1-6 have a priority date of March 5, 1999. The claims of Application No. 10/305,435 thus do not anticipate claims 1-6 and therefore it is not “unclear who is the inventor.” The Office cannot meet its burden to show that the invention was derived from another. Furthermore, it is the claims that “particularly [point] out and distinctly [claim] the subject matter which the applicant regards as his invention or discovery.” *M.P.E.P.* 608.01(i), *see also* 37 *CFR* 1.75(a). Amended claims 1-6 of this application are distinguishable from the claims of co-pending application No. 10/305,435. The fact that different inventive entities are listed on the two applications should not be surprising because the two applications have different claim sets

and therefore are different inventions with different inventive entities. Therefore, no uncertainty exists as to who the inventors of the two applications are. Accordingly, applicants respectfully request the withdrawal of the 35 U.S.C. § 102(f) rejections of claims 1-6 and reconsideration of same.

**Judicially Created Doctrine of Obviousness-Type Double Patenting Rejections**

Claims 1-6 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,869,936. Although the Applicants do not agree with the Office's interpretation of claims 1-6 and claims 1 and 2 of U.S. Patent. 6,869,936, to expedite prosecution, a terminal disclaimer is filed herewith.

**Judicially Created Doctrine of Obviousness-Type Double Patenting Rejections**

Claim 6 stands provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25 and 26 of co-pending Application No. 10/305,435. Applicants duly note the provisional rejection of claim 6 under the judicially created doctrine of obviousness-type double patenting. Applicants will address the provisional rejection upon issuance of Application No. 10/305,435.

**Conclusion**

The claims are believed to be in condition for allowance. Should the Office determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact applicants' undersigned attorney.

Serial No. 10/783,510

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Daniel J. Morath", with a stylized flourish at the end.

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